



Exhibit B

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,

Plaintiff,

v.

ADVANCED CARDIOVASCULAR  
SYSTEMS, INC., GUIDANT  
CORPORATION, ARTERIAL  
VASCULAR ENGINEERING, INC.,  
BOSTON SCIENTIFIC CORPORATION,  
and SCIMED LIFE SYSTEMS, INC.

Defendants.

ADVANCED CARDIOVASCULAR  
SYSTEMS, INC.,

Counterplaintiff,

v.

CORDIS CORPORATION and  
EXPANDABLE GRAFTS  
PARTNERSHIP,

Counterdefendants.

Civil Action No. 97-550-SLR  
(Consolidated)

DOCKETED

JUN 16 11 57 AM '99  
U.S. DISTRICT COURT  
DISTRICT OF DELAWARE

FILED

LITIGATION CALENDAR

JUN 17 1999

FULWIDER, PATTON,  
LEE & UTECHT, LLP

**ANSWER AND COUNTERCLAIM OF DEFENDANT  
ADVANCED CARDIOVASCULAR SYSTEMS, INC.**

Defendant Advanced Cardiovascular Systems, Inc. ("ACS") hereby answers the Third Amended Complaint And Demand For Jury Trial of Plaintiff Cordis Corporation ("Cordis") and

counterclaims against Cordis and Expandable Grafts Partnership ("EGP") in the above-identified action as follows:

**ANSWER**

1. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of the Complaint, and therefore, denies each and every one of those allegations.

2. ACS admits that Advanced Cardiovascular Systems, Inc. is a corporation organized and existing under the laws of the State of California, and has its principal place of business in California. ACS admits that ACS is doing business by supplying its products within this judicial district. ACS denies each and every one of the remaining allegations contained in paragraph 2 of the Complaint.

3. ACS admits that Guidant Corporation is a corporation organized and existing under the laws of the State of Indiana. ACS denies each and every one of the remaining allegations contained in paragraph 3 of the Complaint.

4. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 4 of the Complaint, and therefore denies each and every one of those allegations.

5. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 5 of the Complaint, and therefore denies each and every one of those allegations.

6. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 6 of the Complaint, and therefore denies each and every one of those allegations.

7. ACS admits that Cordis purports to bring this action under the Patent Laws of the United States, Title 35, United States Code, but denies that this action properly arises under the Patent Laws. ACS admits that Cordis purports to base jurisdiction on the statutes cited in paragraph 7 of the Complaint, but denies that jurisdiction over Cordis' causes of action properly lies with this Court. ACS denies each and every one of the remaining allegations contained in paragraph 7 of the Complaint.

8. ACS admits that venue is proper for Advanced Cardiovascular Systems, Inc. assuming the Court finds that jurisdiction is proper, but denies each and every one of the remaining allegations contained in paragraph 8 of the Complaint.

9. ACS incorporates by reference its answers, set forth above, to each allegation in each paragraph incorporated by reference in paragraph 9 of the Complaint.

10. Based upon information and belief, ACS admits that U.S. Patent No. 4,733,762 entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft"(the "'762 patent") issued on April 26, 1988, and that a copy of that patent was attached to the Complaint as Exhibit A. Based upon information and belief, ACS admits that Reexamination Certificate B1 4,733,762 of the '762 patent (the "'762 reexam") issued on October 27, 1998, and that a copy of the '762 reexam was attached to the Complaint as Exhibit B. ACS denies each and every one of the remaining allegations contained in paragraph 10 of the Complaint.

11. Based upon information and belief, ACS admits that U.S. Patent No. 5,102,417 entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft"(the "417 patent") issued on April 7, 1992, and that a copy of that patent was attached to the Complaint as Exhibit C. ACS denies each and every one of the remaining allegations contained in paragraph 11 of the Complaint.

12. Based upon information and belief, ACS admits that U.S. Patent No. 5,195,984 entitled "Expandable Intraluminal Graft"(the "984 patent") issued on March 23, 1993, and that a copy of that patent was attached to the Complaint as Exhibit D. ACS denies each and every one of the remaining allegations contained in paragraph 12 of the Complaint.

13. Based upon information and belief, ACS admits that U.S. Patent No. 5,902,332 entitled "Expandable Intraluminal Graft"(the "332 patent") issued on May 11, 1999, and that a copy of that patent was attached to the Complaint as Exhibit E. ACS denies each and every one of the remaining allegations contained in paragraph 13 of the Complaint.

14. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 14 of the Complaint, and therefore denies each and every one of those allegations.

15. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 15 of the Complaint, and therefore denies each and every one of those allegations.

16. ACS admits that ACS is engaged in the business of making and selling stents including the MultiLink, Duet, and Megalink stents for implantation in human vessels, but denies each and every one of the remaining allegations contained in paragraph 16 of the Complaint.

17. Based on information and belief, ACS admits that AVE is making, offering for sale, and/or selling within the United States stents (including the Micro Stent II and GFX stents) for implantation in human vessels and arteries, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 17 of the Complaint, and therefore denies each and every one of those allegations.

18. Based on information and belief, ACS admits that BSC and SciMed are offering for sale and/or selling within the United States and/or importing into the United States, stents (including the NIR stent) for implantation in human vessels and arteries, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 18 of the Complaint, and therefore denies each and every one of those allegations.

19. ACS denies that Cordis has been, or continues to be, damaged by any purported infringement by ACS or Guidant, and denies that ACS or Guidant or either of them has infringed the '762, '417 or '332 patents or the '762 reexam. ACS is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 19 of the Complaint, and therefore denies each and every one of those allegations.

20. ACS denies that ACS or Guidant or either of them has willfully infringed the '762, '417 or '332 patents, or the '762 reexam. ACS is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 20 of the Complaint, and therefore denies each and every one of those allegations.

### AFFIRMATIVE DEFENSES

21. ACS has not infringed and is not infringing, actively inducing others to infringe, or contributing to the infringement of the claims of the '762 patent, the '762 reexam, the '417 patent, or the '332 patent under any theory of literal infringement or infringement under the doctrine of equivalents.

22. By reason of the state of the prior art and proceedings in the U.S. Patent and Trademark Office during prosecution of the applications which resulted in the issuance of the '762, '417 and '332 patents, and the '762 reexam, including the amendments of claims and arguments and other statements made during the prosecution by or on behalf of the patentee, Cordis is estopped to assert that ACS has infringed or is infringing the claims of the '762, '417 and '332 patents, and the '762 reexam.

23. The '762, '417 and '332 patents, and the '762 reexam are all invalid for failure to comply with the requirements of Part II of Title 35 of the United States Code including, inter alia, the requirements of 35 U.S.C. §§ 102, 103, and 112.

24. The '762 reexam also is invalid for failure to comply with the requirements of Parts II and III of Title 35 of the United States Code including, inter alia, the prohibited introduction of new matter under 35 U.S.C. §§ 112, 132, and impermissibly attempting to broaden the scope of the claims in violation of 35 U.S.C. § 305.

25. Cordis is barred in whole or in part from recovery for the alleged infringement of the '762 reexam and from obtaining injunctive relief against ACS with respect thereto by reason of the doctrine of intervening rights under 35 U.S.C. §§ 252 and 307(b).

26. Cordis is barred, in whole or in part, from recovery for the alleged infringement by ACS or Guidant by reason of Cordis' failure to comply with the requirements of 35 U.S.C. § 287.

27. For having brought the action, Cordis is liable to ACS under 35 U.S.C. § 285.

28. The '762, '417 and '332 patents, and the '762 reexam are unenforceable as a result of acts, omissions, and misrepresentations amounting to inequitable conduct committed during prosecution of the applications in the U.S. Patent and Trademark Office ("PTO") that resulted in the issuance of those patents. On information and belief, the alleged inventors and/or their assignees and licensees, and/or the attorneys prosecuting the applications resulting in the issuance of the '762, '417 and '332 patents, and the '762 reexam, were aware of relevant and material information which was not identified to the PTO at the time of filing or during the prosecution of the applications that led to the issuance of the '762, '417 and '332 patents, and the '762 reexam, and failed to satisfy their uncompromising duty of candor to the PTO under the Code of Federal Regulations 37 C.F.R. 1.56, all of which were part of a pattern intended to deceive the PTO, including at least the following:

(A) Failure to disclose to the PTO during prosecution of U.S. Patent No. 4,733,655 ("the '665 patent"), a predecessor to one or more of the patents in suit, material prior art in the form of an abstract entitled Expandable Intraluminal Graft: A Preliminary Study, by Palmaz et al., which was publicly available in October 1984, more than one year before the patent application for the '665 patent was filed. The applicant then attempted to conceal this omission during prosecution of the '762 patent by excluding abstract related material from the patent specification.

- (B) Deliberately misrepresenting and attempting to deceive the PTO regarding the issues of conception, diligence and reduction to practice by inter alia, submitting a false and misleading Rule 131 affidavit of Palmaz during the First Reexamination of the '665 patent, in an attempt to antedate a prior art patent, namely, U.S. Patent No. 4,560,374 issued to Hammerslag. The Rule 131 affidavit misrepresented the timing of certain dog experiments and was supported with two manuscripts that were misdated by Palmaz, who now admits that those manuscripts were misdated. The Rule 131 affidavit also affirmatively misrepresented that the misdated articles were published in a Radiology journal article when in fact that was not true. Reliance also was placed on a request to use lab animals in an effort to show evidence of diligence when in fact the request to use lab animals was knowingly unrelated to the alleged invention of the '665 patent.
- (C) Failure to disclose to the PTO that Dr. Stewart G. Windeler was at least a co-inventor who had designed the stent covered by the patent claims.
- (D) Failure to disclose to the PTO that Dr. Stanley Carson was at least a co-inventor who had conceived of the idea of placing an expanded metal stent on an angioplasty balloon to be delivered to the point of blockage in a blood vessel and inflated to implant the stent in the vessel.
- (E) Misleading the PTO as to the conception date of the '665 patent in order to antedate prior art cited by the PTO to invalidate the claims when Palmaz stated in a declaration that the conception date for the invention in the '665 application was "at least as early as July of 1980" in contradiction to the invention date previously claimed by him.



(F) Intentionally concealing the best mode known to the alleged inventors of making the claimed slotted tube stent by purposely omitting any reference to Electrical Discharge Machining (EDM) and electropolishing from the patent specifications..

(G) Failing to adequately disclose to the PTO U.S. Patent No. 3,657,744 to Ersek (the "Ersek patent") during prosecution of the '417 patent by wrongfully failing to inform the PTO that the Ersek patent taught the very features that were being represented as not taught by the prior art then being considered by the PTO.

(H) Intentionally burying a critical piece of prior art during prosecution of the claims of the '762 reexam, namely, U.S. Patent No. 4,390,599 to Broyles (the "Broyles patent"), which was buried among approximately three hundred thousand pages of prior art in an effort to obfuscate the record. The Broyles patent was highly relevant because it disclosed a slotted tube that affected the patentability of the claims of the '762 patent, and it was never previously considered by the PTO.

(I) Making material misrepresentations to the PTO during the '762 reexam in a declaration dated July 14, 1998, by George Andros.

(J) Misrepresenting to the PTO during the '762 reexam in a declaration dated March 3, 1993, of John S. Kula that the claimed slotted tube invention did not twist when expanded and therefore had a smooth exterior in order to distinguish over Ersek even though Cordis was aware the contrary was true.

(K) Misrepresenting to the PTO during prosecution of the '332 patent that it was improper to combine teachings relating to balloon expandable stents with that of self-expanding stents to establish obviousness of the '332 patent, when in an earlier

interference proceeding involving the application that matured into the '332 patent, Schatz argued the contrary to the PTO.

29. For the reasons stated above and for additional reasons that ACS expects will be developed in discovery, the '762, '417 and '332 patents, and the '762 reexam are unenforceable under the doctrines of fraud, and/or inequitable conduct in the PTO.

30. Cordis is barred from any recovery by the equitable defenses of laches and unclean hands.

### **COUNTERCLAIM**

By way of a counterclaim against Plaintiff Cordis Corporation ("Cordis") and Expandable Grafts Partnership ("EGP"), Defendant Advanced Cardiovascular Systems, Inc. ("ACS") alleges as follows:

31. This counterclaim arises under the Federal Declaratory Judgment Act and the Patent Laws of the United States, and more particularly under Title 28 U.S.C. §§ 2201 and 2202, and Title 35 U.S.C. §§ 100, et. seq., respectively. Jurisdiction is based on Title 28 U.S.C. §§ 1338 and 2201. Venue is proper in this judicial district under 28 U.S.C. § 1391(b) and (c) and § 1400.

32. Plaintiff Cordis alleges that it is a corporation organized and existing under the laws of the State of Florida having its principal places of business at 40 Technology Drive, Warren, New Jersey and at 14201 N.W. 60<sup>th</sup> Avenue, Miami Lakes, Florida.

33. EGP previously has alleged in this action that it is a partnership organized and existing under the laws of the State of Texas and having an address at 1500 NationsBank Plaza, 300 Convent Street, San Antonio, Texas 78230.

34. ACS is a California corporation having its principal place of business at 3200 Lakeside Drive, Santa Clara, California 95054.

35. Cordis and EGP previously charged ACS and Guidant with infringement of U.S. Patent Nos. 4,733,762 and 5,102,417, and filed a complaint against ACS and Guidant in this action for that alleged infringement on February 6, 1998. A true and correct copy of Cordis' and EGP's Second Amended Complaint herein is attached hereto as Exhibit A.

36. At the time of the Second Amended Complaint, EGP was alleged to hold title to the '762 and '417 patents, subject to a license to Cordis.

37. In response to the Second Amended Complaint, ACS filed a counterclaim against Cordis and EGP, alleging inter alia, that the claims of the '417 and '762 patents were invalid, unenforceable and not infringed, and that the case exceptional, entitling ACS to recover reasonable attorney fees and expenses of litigation against Cordis and EGP pursuant to 35 U.S.C. § 285. A true and correct copy of ACS' Answer and Counterclaim is attached hereto as Exhibit B.

38. Cordis' Third Amended Complaint now alleges that Cordis holds all right, title and interest to the '762 and '417 patents by virtue of an assignment from EGP and seeks to omit EGP as a Plaintiff from this latest complaint. However, such action by Cordis does not relieve Cordis or EGP from liability to ACS for ACS' previously asserted counterclaims, which ACS now repeats and realleges and incorporates herein by reference.

39. In its Third Amended Complaint, Cordis continues to charge ACS with infringement of the '762 and '417 patents. In addition, Cordis now charges ACS with infringement of Reexamination Certificate B1 4,733,762 ("the '762 reexam") and U.S. Patent No. 5,902,332 ("the '332 patent").

40. ACS previously has alleged and continues to allege that U.S. Patent No. 4,733,762, and the claims thereof are invalid, void, and unenforceable, and that ACS has not infringed and is not infringing any of said claims. As part of this allegation, ACS repeats and realleges and incorporates herein by reference, each of the allegations set forth in paragraphs 24-30 above.

41. ACS also has alleged and continues to allege that U.S. Patent No. 5,102,417, and the claims thereof are invalid, void, and unenforceable, and that ACS has not infringed and is not infringing any of said claims. As part of this allegation, ACS repeats and realleges and incorporates herein by reference, each of the allegations set forth in paragraphs 24-30 above.

42. ACS alleges that U.S. Patent No. 5,902,332, and the claims thereof are invalid, void, and unenforceable, and that ACS has not infringed and is not infringing any of said claims. As part of this allegation, ACS repeats and realleges and incorporates herein by reference, each of the allegations set forth in paragraphs 24-30 set forth above.

43. ACS alleges that Reexamination Certificate B1 4,733,762 and the claims thereof are invalid, void, and unenforceable, and that ACS has not infringed and is not infringing any of said claims. As part of this allegation, ACS repeats and realleges and incorporates herein by reference, each of the allegations set forth in paragraphs 24-30 set forth above.

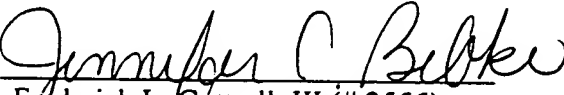
### PRAYER

WHEREFORE, ACS prays for an adjudication against Cordis and EGP as follows:

A. That Cordis take nothing by reason of its Third Amended Complaint and that all counts of the same be dismissed with prejudice;

- B. That the claims of the '762, '417, and '332 patents and the '762 reexam be declared invalid, unenforceable and not infringed by ACS or Guidant;
- C. That Cordis be barred from any recovery because of laches and unclean hands;
- D. That this case be declared exceptional under 35 U.S.C. § 285, and that ACS be awarded its reasonable attorney fees and expenses of litigation against Cordis and EGP;
- E. That ACS be awarded costs of this suit; and
- F. That ACS be awarded such other and further relief as this Court shall deem just and proper.

Dated: June 15, 1999

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